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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,809	02/05/2004	Joel E. Bernstein	812540-610001	5946

28104 7590 12/28/2005

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,809	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in the application as of the amendment filed on October 28, 2005. Of these, claims 1-8 have been withdrawn as drawn to a non-elected invention.

The objection to claim 13 for the grammatically incorrect phrase "administered in a dosage for from about 0.50 grams" is withdrawn in view of Applicant's amendment of the claim. The objection to claim for the abbreviation of the term "NSAIDs" is withdrawn in view of Applicant's amendment of the claim.

Applicant's arguments filed October 28, 2003 regarding the rejection of claims 9-15 under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank Caruso have been fully considered but they are not persuasive. Accordingly, claims 9-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Caruso. In addition, the claims are being newly rejected over U.S. Patent No. 4,579,846 to Crawford et al as submitted by Applicants in the IDS dated October 28, 2005. Please see the arguments below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank S. Caruso, published November 12, 1998.

Caruso teaches treating neuropathic pain with a composition having an antidepressant (see abstract, in particular.) Caruso teaches that the antidepressant can be a tricyclic antidepressant such as imipramine hydrochloride, doxepin hydrochloride, among others (see page 4, lines 1-19, in particular.) Caruso teaches that an oral method of administration can be employed, and the composition may be provided as tablets or hard capsules, which are pharmaceutically acceptable vehicles (see page 6, lines 5-12, in particular.) Caruso furthermore teaches that the composition can have a non-narcotic analgesic such as acetaminophen or naproxen (see page 7, lines 10-24, in particular.) Caruso also teaches that the composition can be formulated to provide a desired dosage level of the components per day, and teaches formulating with pharmaceutically acceptable ingredients and excipients (carriers) (see page 5, lines 20-25 and page 6, lines 10-25, in particular.)

It is respectfully noted that for the purposes of searching for and applying prior

art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 9-15, Caruso teaches exemplary tablet dosage forms having antidepressant drugs and an additional active component that is a non-narcotic analgesic (see page 10, lines 5-37, in particular.) Regarding claims 11-12 and 14-15, Caruso teaches that the tablet form can comprise compositions with 25 mg of imipramine hydrochloride and 325 mg of aspirin or acetaminophen (see examples 36 and 37, in particular.) Thus, Caruso teaches the composition having the claimed tricyclic antidepressant compounds and non-narcotic analgesics, and also teaches the claimed pharmaceutically acceptable vehicle.

Regarding claims 9-10, Caruso's teaching of 25 mg of imipramine hydrochloride in considered to meet the limitation of being a "low dose" of tricyclic antidepressant compound as claimed, because it falls within the range of "about 25 mg/day or less," in accordance with the definition of the "low dose" as set forth by Applicants in the first full paragraph on page 3 of the specification. Caruso's teaching thus also meets the limitation of being from "about" 2.5 mg to "about" 25 mg daily as recited in claim 10.

Regarding claims 9 and 13, Caruso's teaching of 325 mg of acetaminophen is considered to meet the limitation of being a "standard dose" of non-narcotic analgesic

compound as claimed, because it falls within the range of "about 0.5 grams to about 2.6 grams," in accordance with the Applicants' guidance of a suitable "standard dose," which is set forth in the second full paragraph on page 3 of Applicants' specification. In particular, 325 mg of acetaminophen is considered to be within the range of "about" 0.5 grams to "about" 2.6 grams, as set forth by Applicants.

Accordingly, the tablet dosage forms taught by Caruso anticipate the compositions of claims 9-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,579,846 to Crawford et al, issued April 1, 1986, in view of U.S. Patent No. 4,434,164 to Joseph G. Lombardino, issued February 28, 1984.

Crawford et al. teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-

inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant) (see abstract and column 3, lines 45-58, in particular.) Crawford et al. teaches that the piroxicam can be provide in a range of 0.1 to 1 mg/kg/day, whereas the second ingredient, such as doxepin, can be provided separately in an amount that is generally lower than the dosages typically specified in the prior art (see column 3, lines 45-55, in particular.) Crawford et al. also teaches that in a combined formulation, the proportion of each drug is the ratio of the total daily dosage of each drug when dosed alone (see column 3, lines 55-68, in particular.) That is, Crawford et al. teaches that the combined formulation could comprise the (i) 0.1 mg/kg/day dose of piroxicam with (ii) the lower dose of doxepin that is taught by Crawford et al. as being provided if the drugs are administered alone (i.e. not in combination, separately.) Crawford et al. also exemplifies a treatment composition comprising 20 mg of piroxicam and 20 mg doxepin with lactose and hydroxypropyl methylcellulose (carriers), and teaches that a dosage of the piroxicam can be from 5-50 mg/day (see Example 9 and column 4, lines 1-10, in particular.)

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Crawford et al. does not specifically teach that the compositions as exemplified comprise a "standard dose" of a non-narcotic analgesic and a low dose of a tricyclic antidepressant, as recited in claim 9.

Lombardino teaches novel salts of piroxicam that provide anti-inflammatory activity (see column 1 line 1 through column 2 line 60, in particular.) Lombardino teaches that a suitable dose of the piroxicam salt can be from 5 mg up to 1000 mg per day (see column 3, liens 18-25, in particular.)

Accordingly, Crawford et al's dosage of 5 to 50 mg/day (see column 4, lines 1-10, in particular), falls within the dosage range as taught by Lombardino et al. to be useful for anti-inflammatory action, and thus is considered to be a "standard dose" of piroxicam. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the "standard" normal dose of piroxicam as taught by Crawford et al. and Lombardino, with a lower dose of doxepin, as taught by Crawford et al, with the expectation of providing a suitable anti-inflammatory composition for the treatment of gastric irritation.

Regarding claim 10, Crawford et al. teaches that the dosage of doxepin can be from 4 to 200 mg/day (see column4, lines 5-10, in particular), and exemplifies a composition with 20 mg, and thus meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would

have found it obvious to vary and/or optimize the amount of doxepin provided in the composition, according to the guidance provided by Crawford et al, to provide a composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 11, Crawford et al. teaches providing doxepin, as recited in the claim. Regarding claim 12, Crawford et al. teaches that doxepin is marketed in the form of its hydrochloride salt (see column 3, lines 15-20, in particular), and thus it would be obvious to one of ordinary skill in the art to provide doxepin hydrochloride because Crawford et al. teaches that this is a doxepin form that available on the market. Regarding claim 14, Crawford et al. teaches providing piroxicam, which is a non-steroidal anti-inflammatory. Regarding claim 15, Crawford et al. teaches that the composition can be provided as a tablet or capsule (see column 4, lines 15-20, in particular.)

Response to Amendment

Applicant's arguments filed October 28, 2003 regarding the rejection of claims 9-15 under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank Caruso have been fully considered but they are not persuasive. Accordingly, claims 9-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Caruso. In addition, the claims

are being newly rejected over U.S. Patent No. 4,579,846 to Crawford et al and U.S. Patent No. 4,434,164 to Lombardino.

Regarding Applicant's argument that the composition is consisting essentially of, rather than comprising, the claimed components, it is noted that the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising" for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, as discussed above. See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding Applicant's arguments that claim 10 recites that the composition is provide in a daily dose form of from about 2.5-25 mg daily, it is noted that Caruso is concerned with the formulation of daily dosage forms (see page 5, lines 20-25, in particular.) Furthermore, it is noted that a recitation of the intended use of the claimed invention, such as daily administration must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, Caruso teaches the composition as claimed in Examples 36-37, for example, and thus it is considered that the unit dosage forms as taught by Caruso would also be capable of daily administration.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER